



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0624]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notice of Participation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0191. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notice of Participation--21 CFR 12.45 (OMB Control Number 0910-0191)--Extension

Section 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e), the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the pre-hearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

In the Federal Register of September 9, 2011 (76 FR 55918), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
12.45	4	1	4	3	12

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years.

Dated: March 20, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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